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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,406	10/12/2001	Arnold Neracher	NERA-2	3542
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KRIEG DEVAULT LLP				
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EXAMINER				
CAMPBELL, VICTORIA P				
ART UNIT		PAPER NUMBER		
3763				
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09/10/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/976,406

Applicant(s)

NERACHER, ARNOLD

Examiner

VICTORIA P. CAMPBELL

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-111 is/are pending in the application.
- 4a) Of the above claim(s) 70-72, 75, 78, 79, 83-100 and 103-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68, 69, 73, 74, 76, 77, 80-82, 101 and 102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 09/976406 application filed October 12, 2001. Claims 68, 69, 73, 74, 76, 77, 80-82, 101, and 102 as amended are currently pending and considered below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 68,73,77 and 80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Willis (USPN 2,590,138). Willis discloses a container (1) and a primary source of potential energy (17) being a substance compressible under pressure. The compressible substance is an elastic solid (see spring #17). The compressible substance is put under pressure by reducing the volume that it, the spring, takes up in the container. See figure 2. The container has a piston (7) that is a moveable member and encloses the compressible substance on one side of the housing. See figure 2. The piston is configured to move to transmit pressure after retaining means rod (21) has been released. See figure 3.
2. Claims 68-69,73-74,77,80 and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Kriesel (USPN 5,743,879). Kriesel discloses a container and a primary

source of potential energy (48) being a substance compressible under pressure. The compressible substance is an elastic polydimethylsiloxane (see 6:8). The compressible substance is put under pressure by reducing the volume that it takes up in the container. See figure 5. The container has a piston (48c) that is a moveable member and encloses the compressible substance on one side of the housing. See figure 1. The container is an injector for drug or medicament into the body. Since the compressible substance is a polysiloxane, it meets the compressibility properties as claimed.

3. Claims 68,73,77,80-81 and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilmot (USPN 5,391,151). Wilmot discloses a container and a primary source of potential energy (5) being a substance compressible under pressure. The compressible substance is an elastic solid (see spring #5). The compressible substance is put under pressure by reducing the volume that it, the spring, takes up in the container. The container has a piston (4) that is a moveable member and encloses the compressible substance on one side of the housing. See figure 1. The piston is configured to move to transmit pressure after retaining means has been released. See 3:31-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 76 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmot. Wilmot meets the claim limitations as described above but fails to specifically disclose the pressure of the compressible substance to be at least 200 bars prior to use and a fluid jet of supersonic speed. However, at the time of the invention, it would have been obvious by one in the art to consider the device of Wilmot to have a pressure of at least 200 bars that would result in a fluid jet of supersonic speed. Wilmot teaches that powered injectors generate a high pressure such as 600 bars or more. See Wilmot 1:59+. This pressure would result in a jet of supersonic speed.

Response to Arguments

5. Applicant's arguments filed January 12, 2006 have been fully considered but they are not persuasive.

6. Regarding applicant's argument that the devices of Willis, Kriesel, and Wilmot do not have orifices sized to create jets enabling subcutaneous or intracutaneous delivery of fluid, the examiner disagrees. The examiner notes that subcutaneous or intracutaneous delivery of the fluid of Willis, Kriesel, and Wilmot could be accomplished by use of needles or catheters attached to the dispensing orifices. Furthermore, the examiner notes that injection speed is not something that can be inferred from a drawing. Additionally, the examiner notes that the devices of the prior art need only have an orifice capable of creating a jet (which the examiner notes could have any

velocity) enabling subcutaneous delivery, as the phrase "that is sized to create" has been interpreted by the examiner to be language which is functional in nature.

7. Regarding applicant's argument that the spring of Willis is not a solid as commonly used in the English language, the examiner vehemently disagrees. The spring itself is a coil comprised of a solid material. The definition of "solid" according to the Merriam-Webster Online Dictionary is "a substance that does not flow perceptibly under moderate stress, has a definite capacity for resisting forces (as compression or tension) which tend to deform it, and under ordinary conditions retains a definite size and shape" and as such the spring of Willis fits the definition and therefore the limitations of the claim.

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., injection of fluid without a needle) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner further notes that injections of 200 bars or at supersonic speed may still be performed through a needle or other subcutaneous cannula.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763